

# EXHIBIT B

**LAW OFFICES ROSEMARIE ARNOLD**  
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**Attorneys for Plaintiff**

**UNITED STATES DISTRICT COURT**  
**DISTRICT OF MASSACHUSETTS**

<p>Plaintiff,</p> <p><b>BERNADETTE EFFENDIAN</b></p> <p>vs.</p> <p>Defendants,</p> <p><b>NEW ENGLAND COMPOUNDING PHARMACY, INC. d/b/a NEW ENGLAND COMPOUNDING CENTER, PREMIER ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTHERN NEW JERSEY, LLC, also trading as PREMIER ORTHOPAEDIC ASSOCIATES, PREMIER ORTHOPPAEDIC ASSOCIATES SURGICAL CENTER, LLC, KIMBERLEY YVETTE SMITH, M.D. a/k/a KIMBERLEY YVETTE SMITH-MARTIN, M.D., THOMAS A. DWYER, M.D., JOHN DOE(S) CORPORATIONS 1-4 and JOHN DOE(S), M.D. 1-4</b></p>	<p><b>Case No.: 1:13-cv-02568-RMB-JS</b></p> <p><b>MDL No. 1:13-md-2419-FDS</b></p> <p><b>THIRD AMENDED COMPLAINT</b></p> <p><b>PLAINTIFF DEMANDS TRIAL BY JURY</b></p>
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Plaintiff, **BERNADETTE EFFENDIAN**, residing at 800 College Drive in the City of Vineland, County of Cumberland and State of New Jersey, by way of Amended Complaint against the Defendants, says:

**PARTIES**

1. At all times hereinafter mentioned, Defendant, **New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center** (hereinafter referred to as “NECC”), is a corporation duly organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with its principal place of business located at 697 Waverly Street, Framingham, MA 01701.

2. At all times mentioned herein and material hereto, Defendant NECC, was in the business of manufacturing, compounding, marketing and selling medications such as methylprednisolone acetate, an injectible steroid.

3. Defendant, **Premier Orthopaedics and Sports Medicine Associates of Southern New Jersey, LLC, also trading as Premier Orthopaedics** (hereinafter referred to as “Premier Orthopaedics”) is a corporation, medical institution and medical facility, duly organized and existing under and by virtue of the laws of the State of New Jersey, with its principal place of business located at 298 S. Delsea Drive, Vineland, New Jersey 08360.

4. At all time mentioned herein and material hereto, Defendant, Premier Orthopaedics, held itself and its agents, servants, workers, representatives, physicians, nurses, staff., contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medial care and services to patients such as Plaintiff, Bernadette Effendian,

5. Defendant, **Premier Orthopaedic Associates Surgical Center, LLC** (hereinafter referred to as “Surgical Center”) is a corporation, medical institution and medical facility, duly organized and existing under and by virtue of the laws of the State of New Jersey, with its principal place of business located at 352 Delsea Drive, Vineland, New Jersey 08360.

6. At all times mentioned herein and material hereto, Defendant, Surgical Center, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Bernadette Effendian.

7. Defendants, **John Doe Corporations 1-4**, are corporations, medical facilities and/or medical practice groups, duly organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts and/or the State of New Jersey, with their principal places of business at unknown addresses, whose true names are unknown to Plaintiff and are being sued by Plaintiffs under fictitious names.

8. At all times mentioned herein and material hereto, Defendants John Doe 1-4, held themselves and their agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Bernadette Effendian.

9. Defendant **Kimberley Yvette Smith, M.D. a/k/a Kimberley Yvette Smith-Martin, M.D.** (hereinafter “Dr. Smith”) and **THOMAS A. DWYER, M.D.** (hereinafter “Dr. Dwyer”), is and/or were duly licensed physicians, who at all times mentioned herein and material hereto, was a practicing physician in the state of New Jersey, a member of the staff of Defendant Premier Orthopaedics and/or Defendant Surgical Center and/or Defendant John Doe Corporations 1-4, and was an agent, ostensible agents, servant, representative and/or employee of Defendants Premier Orthopaedics and/or Surgical Center and/or John Doe Corporations 1-4.

10. At all times mentioned herein and material hereto, Defendants, Dr. Smith and/or Dr. Dwyer represented themselves to be competent, skillful and qualified physicians, qualified to practice, attend, treat and administer medical care and treatment upon and to patients such as Plaintiff, Bernadette Effendian.

11. Defendants, **John Doe(s), M.D. 1-4**, are duly licensed physicians, who at all times mentioned herein and material hereto, was a practicing physicians in the state of New Jersey, members of the staff of Defendant Premier Orthopaedics and/or Defendant Surgical Center and/or Defendant John Doe Corporations 1-4, and were agents, ostensible agents, servants, representatives and/or employees of Defendants Premier Orthopaedics and/or Surgical Center and/or John Doe Corporations 1-4, whose true names are unknown to Plaintiff and are being sued by Plaintiff under fictitious names.

12. At all times mentioned herein and material hereto, Defendants, John Doe(s), M.D. 1-4, represented themselves to be competent, skillful and qualified physicians, qualified to practice, attend, treat and administer medical care and treatment upon and to patients such as Plaintiff, Bernadette Effendian.

### FACTS

13. On September 19, 2012, Plaintiff Bernadette Effendian, received an epidural lumbar steroid injection to ease her back pain; said injection was administered by Defendant, Dr. Smith, at Defendant, Surgical Center.

14. The injectible steroid received by Plaintiff Bernadette Effendian, on September 19, 2012, was methylprednisolone acetate, which was manufactured and/or compounded and/or sold by Defendant NECC.

15. On October 3, 2012, Plaintiff Bernadette Effendian, received a second lumbar epidural steroid injection; said injection was also administered by Defendant, Dr. Smith, at Defendant, Surgical Center.

16. The injectible steroid received by Plaintiff, Bernadette Effendian, on October 3, 2012, was also methylprednisolone acetate, which was manufactured and/or compounded and/or sold by Defendant. NECC.

17. On or about September 26, 2012 and/or October 6, 2012, Defendant NECC, recalled the injectible steroid as it was determined that the injectible steroid compounded by Defendant, NECC, was contaminated with a fungus.

18. Sometime thereafter, Plaintiff, Bernadette Effendian, was contacted and advised that the epidural steroid injections administered by Defendant, Dr. Smith, in September and October of 2012, had come from specific lot numbers of methylprednisole acetate manufactured, compounded and/or sold by Defendant NECC, and was contaminated with a fungus.

19. Since receiving the contaminated epidural steroid injections, Plaintiff Bernadette Effendian, has suffered with severe disabling injuries, both physical and emotional, including, but not limited to spinal fungal meningitis and paraspinal abscesses. .

20. Based upon information disclosed by the US Centers for Disease Control and Prevention (hereinafter referred to as "CDC"), Plaintiff, Bernadette Effendian, is now at increased risk of having additional severe medical problems in the future and continues to suffer severe pain and other serious medical complications.

### **COUNT I**

#### **VIOLATIONS OF THE PRODUCT LIABILITY ACT N.J. STAT. §2a:58c-1 TO 7.**

21. Plaintiff incorporates by reference all aforementioned paragraphs of this Complaint, the same as if fully set forth at length herein.

22. Defendants, NECC, Premier Orthopaedics, Surgical Center, Dr. Smith, Dr. Dwyer and John Doe Corporations 1-4 were the manufacturers and/or sellers of doses of methylprednisolone acetate steroid administered to Plaintiff, Bernadette Effendian, that were contaminated with a fungus.

23. Defendants harmed Plaintiff through the manufacture and/or sale of a methylprednisolone acetate steroid product that was not reasonably fit, suitable or safe for its intended purpose because it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.

24. Defendants harmed Plaintiff by failing to contain adequate warnings or instructions

with the methylprednisolone acetate steroid product, and/or designing the product in a defective manner. As a result, Plaintiff suffered personal physical injury, as well as pain and suffering, mental anguish and emotional harm.

25. By reason of the defective product manufactured or sold by Defendants as aforesaid, Plaintiff Bernadette Effendian, was caused to sustain serious and disabling personal, permanent injuries including, but not limited to, spinal meningitis and paraspinal abscesses, she was caused to undergo further treatment; she has suffered extreme anxiety, pain, and suffering, loss of life's pleasures and other emotional distress; she has in the past and may in the future be compelled to spend money and incur obligations for further medical care and treatment; she has in the past and may in the future continue to suffer with pain and mental anguish; she is at increased risk of having additional severe medical problems in the future; she has and will suffer an impairment of her future earning capacity; she has been and will in the future be disabled from performing her usual duties and avocations, all to her great loss and detriment.

26. As a result of her exposure to the defective product as set forth above, Plaintiff suffered and continues to suffer pain, mental anguish and emotional distress, loss of enjoyment of life's pleasures, embarrassment and humiliation.

WHEREFORE, Plaintiff, Bernadette Effendian, claims of Defendants, New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center; Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, also trading as Premier Orthopaedic Associates; Premier Orthopaedic Associates Surgical Center, LLC, Kimberley Yvette Smith, M.D. a/k/a Kimberley Yvette Smith-Martin, M.D. and/or Thomas A. Dwyer, M.D. and John Doe Corporations 1-4, and each of them respectively, individually, jointly and severally, separate sums and damages and brings this action to recover same.

**COUNT II – NEGLIGENCE**

27. Plaintiff incorporates by reference all aforementioned paragraphs of this Complaint, the same as if fully set forth at length herein.

28. At all times mentioned herein, Defendants, NECC and John Doe Corporations 1-4 had a duty to exercise reasonable care in the manufacture, sale and/or distribution of methylprednisolone acetate steroid doses into the stream of commerce, including a duty to ensure that the product did not cause patients such as Plaintiff, Bernadette Effendian, to be subject to an unsafe product and to be at an increased risk of contracting meningitis.

29. Defendants, NECC and John Doe Corporations 1-4 failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control and/or distribution of methylprednisolone acetate into interstate commerce and Defendants knew or should have known that the lot numbers of the methylprednisolone acetate at issue created a high risk of harm.

30. Defendants, NECC and John Doe Corporations 1-4 were negligent in the design, manufacture, compounding, testing, warning, marketing and selling of the lot numbers of methylprednisolone acetate at issue, in that they:

- a) failed to use due care in designing, compounding and/or manufacturing the methylprednisolone acetate so as to avoid harming individuals;
- b) failed to conduct adequate testing to determine the safety of methylprednisolone acetate prior to distributing it to the public;
- c) failing to properly retain competent employees to compound the methylprednisolone acetate properly so as to avoid harming the public;



- d) failing to maintain adequate quality control in the manufacturing and compounding of the methylprednisolone acetate to avoid haring the public; and
- e) providing an injectible steroid which was below the standard of care in the community, thereby increasing the risk of harm to Plaintiff Bernadette Effendian's wellbeing;

31. By reasons of the carelessness, recklessness and negligence of the Defendants as aforesaid, Plaintiff Bernadette Effendian, was caused to sustain serious and disabling personal, permanent injuries including, but not limited to spinal fungal meningitis and paraspinal abcesses; she was caused to undergo further treatment; she has suffered extreme anxiety, pain and suffering, loss of life's pleasures and other emotional distress; she has in the past and may in the future be compelled to spend money and incur obligations for further medical care and treatment; she has in the past and may in the future continue to suffer with pain and mental anguish; she is at increased risk of having additional severe medical problems; she has and will suffer an impairment of her future earning capacity; she has been and will be in the future disabled from performing her usual duties and avocations, all to her great loss and detriment.

32. As a result of the negligence of the Defendants as set forth above, Plaintiff Bernadette Effendian suffered and continues to suffer pain, mental anguish and emotional distress, loss of enjoyment of life's pleasures, embarrassment and humiliation.

**WHEREFORE**, Plaintiff Bernadette Effendian, claims of Defendants, New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, John Doe Corporations 1-4, and each of them respectively, individually, jointly and severally, separate sums and damages and brings this action to recover same.

**COUNT III – NEGLIGENCE**

33. Plaintiff incorporates by reference all aforementioned paragraphs of this Complaint, the same as if fully set forth at length herein.

34. At all times mentioned herein, Plaintiff's physicians and healthcare providers, Defendants, Premier Orthopaedics, Surgical Center, Dr. Smith, Dr. Dwyer, John Doe Corporation 1-4 and John Doe(s), M.D. 1-4, respectively, individually, jointly and severally, were charged with the professional responsibility of rendering proper medical care and treatment to Plaintiff, and of assuring that proper medical care, attention and treatment would be provided to Plaintiff during all times which she remained under Defendants' medical care and treatment.

35. Defendants, Premier Orthopaedics, Surgical Center, Dr. Smith, Dr. Dwyer, John Doe Corporations 1-4 and John Doe(s), M.D. 104, respectively, individually and severally, by and through their separate and respective agents, ostensible agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless and negligent in:

- a) providing an injectible steroid which was below the standard of care in the community, thereby increasing the risk of harm to Plaintiff Bernadette Effendian's wellbeing; and
- b) utilizing the methylprednisolone acetate manufactured and/or compounded by Defendant, NECC, which they knew or should have known was defective and/or contaminated.

36. By reason of the carelessness, recklessness and negligence of the Defendants as aforesaid, Plaintiff Bernadette Effendian, was caused to sustain serious and disabling personal, permanent injuries including, but not limited to spinal fungal meningitis and paraspinal abscesses;

she was caused to undergo further treatment; she has suffered extreme anxiety, pain and suffering, loss of life's pleasures and other emotional distress; she has in the past and may in the future be compelled to spend money and incur obligations for further medical care and treatment; she has in the past and may in the future continue to suffer with pain and mental anguish; she is at increased risk of having additional severe medical problems; she has and will suffer an impairment of her future earning capacity; she has been and will be in the future disabled from performing her usual duties and avocations, all to her great loss and detriment.

37. As a result of the negligence of the Defendants as set forth above, Plaintiff Bernadette Effendian suffered and continues to suffer pain, mental anguish and emotional distress, loss of enjoyment of life's pleasures, embarrassment and humiliation.

**WHEREFORE**, Plaintiff Bernadette Effendian, claims of Defendants, Premier Orthopaedics and Sports Medicine Associates of Southern New Jersey, LLC, also trading as Premiere Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberley Yvette Smith, M.D., Thomas A. Dwyer, M.D., John Doe Corporations 1-4, and each of them respectively, individually, jointly and severally, separate sums and damages and brings this action to recover same.

#### **COUNT IV – BREACH OF EXPRESS WARRANTY**

38. Plaintiff incorporates by reference all aforementioned paragraphs of this Complaint, the same as if fully set forth at length herein.

39. Defendants NECC and Joe Doe Corporations 1-4, expressly warranted that the methylpredisolone acetate was safe.

40. Defendants NECC and John Doe Corporations 104, did not conform to their expressed representations because the methylprednisolone acetate was not safe.

41. As a direct and proximate result of the breach of said warranties, Plaintiff Bernadette Effendian, was caused to suffer injuries including, but not limited to spinal fungal meningitis and paraspinal abscesses; she was caused to undergo further treatment; she has suffered extreme anxiety, pain and suffering, loss of life's pleasures and other emotional distress; she has in the past and may in the future be compelled to spend money and incur obligations for further medical care and treatment; she has in the past and may in the future continue to suffer with pain and mental anguish; she is at increased risk of having additional severe medical problems; she has and will suffer an impairment of her future earning capacity; she has been and will be in the future disabled from performing her usual duties and avocations, all to her great loss and detriment.

42. By reasons of the carelessness, recklessness and negligence of the Defendants as aforesaid, Plaintiff Bernadette Effendian, was caused to sustain serious and disabling personal, permanent injuries including, but not limited to

**WHEREFORE**, Plaintiff Bernadette Effendian, claims of Defendants, New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, John Doe Corporations 1-4, and each of them respectively, individually, jointly and severally, separate sums and damages and brings this action to recover same.

**JURY DEMAND**

Plaintiff demands a trial by jury on all issues so triable.

**DESIGNATION OF TRIAL COUNSEL**

Evan D. Baker, Esq. is designated as trial counsel.

**CERTIFICATION**

I hereby certify that this matter is not the subject of any other action pending in any court or arbitration proceeding, that no such other action or arbitration proceeding is contemplated by this Plaintiff, and that there are no other parties, whom, to the knowledge of the Plaintiff's counsel, should be joined in this action.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

LAW OFFICES ROSEMARIE ARNOLD

Date: October 30, 2014

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EVAN D. BAKER